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Dated: 7-1-, 2003

Signature:

Linda Bourg
LINDA BOURG

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Nicholas Bachynsky

Woodie Roy

Serial No.: 09/744622 (PCT/US99/16940)

Filed: January 26, 2001

For: **CHEMICALLY INDUCED
INTRACELLULAR HYPERTHERMIA**

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Group Art Unit: Unknown

Examiner: Unassigned

Atty. Docket: P01615US1 / 09805783
(U.S. Nat'l. Phase)

DECLARATION IN SUPPORT OF RENEWED PETITION 37 C.F.R. 1.47(B)

I, James Naples, am President of assignee and have full authority to execute the declaration on behalf of the assignee Texas Pharmaceuticals, Inc., a Texas corporation, located at 701 West 14th Street, Texarkana, Texas 75501 ("assignee"). It is noted that Texas Pharmaceuticals has undergone a corporate name change to St. Jude Pharmaceuticals, which was recorded in the USPTO on May 16, 2003.

I have first hand knowledge of the following facts, which show that:

- i) assignee has full proprietary interest in the above-referenced patent application, application number 09/744,622 (PCT/US99/16940) ("the invention"), specifically, the invention has been assigned to assignee, both inventors, Nicholas Bachynsky and Woodie Roy, of the above-referenced patent application ("inventors")

have agreed in writing to assign the invention to assignee, and assignee otherwise has full proprietary interest in the invention of the above-referenced application;

- ii) the priority document (U.S. Provisional Application No. 60/094,286), application number 09/744,622 (based on PCT/US99/16940), and the invention referred to in the sales agreement previously submitted to the USPTO, are identical. The sales agreement executed by the inventors refers to the invention that is described in U.S. Provisional Application No. 60/094,286. PCT/US99/16940, which claims priority to U.S. Provisional Application No. 60/094,286, describes the identical invention. U.S. Application No. 09/744,622 is based on PCT/US99/16940, and thus describes the identical invention;

- iii) the inventors have refused to sign the declaration;

- iv) the inventors signed a declaration in the provisional patent application claimed as a priority document to this application;

- v) I am President of assignee and have full authority to execute the declaration on behalf of assignee; and

- vi) filing the above-referenced patent application under 37 C.F.R. § 1.47(b) is necessary to preserve the rights of the parties and to prevent irreparable damage which otherwise would result with the application becoming abandoned.

The assignee has proprietary interest in the invention

The following written, documentary evidence is being submitted herewith showing that the assignee has full proprietary interest in the invention. I have first hand knowledge of the preparation and execution of all of the submitted documents, which

show that the invention of the above-referenced application has been assigned to assignee, both inventors have agreed in writing to assign the invention to assignee, and assignee otherwise has full proprietary interest in the invention of the above-referenced application.

I. The priority document (U.S. Provisional Application No. 60/094,286), application number 09/744,622 (based on PCT/US99/16940), and the invention referred to in the sales agreement executed by Nicholas Bachynsky previously submitted to the USPTO, are identical.

The sales agreement executed by Nicholas Bachynsky, dated March 8, 1998, covers, in writing, the sale of rights to the invention as disclosed and claimed in the above-referenced patent application, and U.S. Provisional Application No. 60/094,286, to which the instant application claims priority. This is shown, for example, in the Agreement which describes the sold invention as follows:

Seller [Inventor Nicholas Bachynsky], with the financial support of James J. Naples, has been conducting medical research and developing a novel use and method of inducing intracellular hyperthermia and free radical flux through use of dinitrophenol and other mitochondrial uncoupling agents in the treatment of infectious and malignant disease. Seller has developed and devised a therapeutic application of dinitrophenol and other mitochondrial uncoupling agents for such purposes.

This is the same invention as the above-referenced patent application. This can be seen, for example, from the abstract of the instant application, which defines the invention as follows:

An invention relating to therapeutic pharmacological agents and methods to chemically induce intracellular hyperthermia and/or free radicals for the diagnosis and treatment of infections, malignancy and other medical conditions. The invention relates to a process and composition for the diagnosis

or killing of cancer cells and inactivation of susceptible bacteria, parasitic, fungal and viral pathogens by chemically generating heat, and/or free radicals or hyperthermia-inducible immunogenic determinants by using mitochondrial uncoupling agents, especially 2,4 dinitrophenol [dinitrophenol] either alone or in combination with other drugs, hormones, cytokines and radiation.

The abstract of the priority document, U.S. Provisional Application No. 60/094,28, identically describes the invention as described in the instant application:

An invention relating to therapeutic pharmacological agents and methods to chemically induce intracellular hyperthermia and/or free radicals for the diagnosis and treatment of infections, malignancy and other medical conditions. The invention relates to a process and composition for the diagnosis or killing of cancer cells and inactivation of susceptible bacteria, parasitic, fungal and viral pathogens by chemically generating heat, and/or free radicals or hyperthermia-inducible immunogenic determinants by using mitochondrial uncoupling agents, especially 2,4 dinitrophenol [dinitrophenol] either alone or in combination with other drugs, hormones, cytokines and radiation.

Moreover, the working example defining the invention sold in the Agreement, as defined in Schedule 1 to Exhibit A of the Agreement (submitted in the Renewed Petition under 37 CFR 1.47 mailed 27 November 2002), is identical to Example 1 of the above-referenced application (see pages 38 – 40 and Table 15) and identical to Example 1 of the priority document, U.S. Provisional Application No. 60/094,28 (pages 43-45).

II. The priority document (U.S. Provisional Application No. 60/094,286), application number 09/744,622 (based on PCT/US99/16940), and the invention referred to in the sales agreement executed by Woodie Roy previously submitted to the USPTO, are identical.

Attached as Exhibit B to Exhibit 1 of the Renewed Petition under 37 CFR 1.47 mailed 27 November 2002 is an Agreement for Sale of Invention and Related Rights (by

inventor Roy) ("Agreement#2"), wherein inventor Woodie Roy sold all right, title and interest in the invention of the above-referenced patent application to assignee, Texas Pharmaceuticals, Inc. Agreement #2, dated July 20, 1998, was executed by inventor Woodie Roy on July 24, 1998, and by James J. Naples, on behalf of assignee, on July 24, 1998. This agreement was executed well in advance of the filing of the above-referenced patent application on July 27, 1999, and therefore could not include a reference to or identify the application number for the above-referenced patent application.

This document covers, in writing, the sale of rights to the invention as disclosed and claimed in the above-referenced patent application. This is shown, for example, in the Agreement which describes the sold invention as follows:

Seller has assisted [inventor] Nicolas Bachynsky ("Bachynsky") who, with the financial support of James J. Naples, has been conducting medical research and developing a novel use and method of inducing intracellular hyperthermia and free radical flux through use of dinitrophenol and other mitochondrial uncoupling agents in the treatment of infectious and malignant disease. Bachynsky and seller have developed and devised a therapeutic application of dinitrophenol and other mitochondrial uncoupling agents for such purposes.

This is the same invention as the above-referenced patent application, which can be seen by reference to the application's abstract (quoted above).

The invention sold in the Agreement#2 is also defined in Schedule 1 to Exhibit A of the Agreement#2, wherein it is defined as follows:

This invention provides a medical treatment for ... treatment of resistant neoplastic and infectious disease by concurrent administration of dinitrophenol [or other mitochondrial thermoregulatory uncoupling agents ...] ... and specific metabolic, activating cytokines ... hormones... and other medications to control and focally enhance the mitochondrial uncoupling effects. ... A new use(s)/method of

generating intracellular oxygen derived from free radicals, and heating from within the cell [intracellular hyperthermia] has been discovered for dinitrophenol (or other oxidative phosphorylation uncouplers) in prevention of parasites .. bacteria ... viruses... and neoplasia...”

This description of the invention as sold in the Agreement #2 directly matches the invention described in the present application, as can be seen, for example, from the abstract of the application, discussed above.

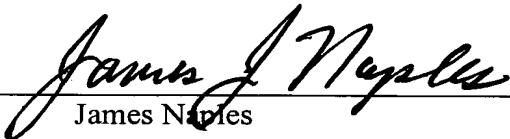
The working example defining the invention sold in the Agreement #2 (submitted in the Renewed Petition under 37 CFR 1.47 mailed 27 November 2002), is identical to Example 1 of the above-referenced application (see pages 38 – 40 and Table 15) and identical to Example 1 of the priority document, U.S. Provisional Application No. 60/094,28 (pages 43-45).

Further still, the description of the invention sold in the Agreement#2, as defined in Schedule 1 to Exhibit A of the Agreement#2, is identical to the description of the invention of the present invention as found in the attachments to the Assignment of inventor Woodie Roy, as filed in this case

I have first hand information and belief that signing the declaration for assignee in lieu of the inventors (filing the application under 37 C.F.R. § 1.47(b)) is necessary in order to preserve the rights of the parties and to prevent irreparable damage which otherwise would result with the application becoming abandoned.

The undersigned being hereby warned that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001, and

that such willful false statements and the like may jeopardize the validity of the application or any patent issuing therefrom, I declare that all statements made herein by my own knowledge are true, and that all statements made herein on information and belief are believed to be true.


James Naples

Date: 6/26/03